

REMARKS

This amendment replaces the amendment and reply under 37 C.F.R. 1.116, filed on May 19, 2008, which was not entered by the Examiner. By the present communication, claims 1 and 18 are amended and claims 29-35 are canceled without prejudice. Claims 16 and 39-42 are withdrawn from consideration although the remarks in the Office Action indicate that Claim 16 will be joined with Species A.

No new matter is presented. Support for the amended claims can be found throughout the application as filed, including, but not limited to paragraphs [0084] and [0086] (legend to Table 1 on p. 44). Upon entry of the amendment, claims 1-28 and 36-44 will be pending. In view of the foregoing amendments and the following remarks, Applicant respectfully requests reconsideration of this application.

As a preliminary matter, Applicant's undersigned representatives thank Examiner Zhou for the courtesies extended during the telephonic interview on July 15, 2008, in which the rejection under 35 U.S.C. § 101 was discussed. Although no agreement with respect to the claims was reached, the amendments and remarks herein are provided for further consideration by the Examiner.

I. Information Disclosure Statement

The Office Action dated February 27, 2007, states that all of the references cited in the Information Disclosure Statement (IDS), filed on 1/5/04 and 9/13/04 have been entered and considered. However, Applicant notes that U.S. Patent No. 6,636,646 on page 1 of the 9/13/04 IDS was not initialed by the Examiner. Accordingly, Applicant respectfully requests that the Examiner consider this reference and initial form PTO-1449 and return a copy to the Applicant.

II. Restriction Requirement and Rejoinder

The Office Action states that "Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election

without traverse.” However, Applicants respectfully point out that in the Restriction Requirement was traversed in part because the “magnitude, quantity, or quality of the data value” for nucleic acid expression, protein expression, and chromatographic profiles is meant to reflect the chemical or biological properties of the sample, *e.g.*, a chemical reaction or a binding interaction or other similar interactions known to those of skill in the art (*see* Specification, paragraph [0022]) (*See* Response to Restriction Requirement, dated December 17, 2007). Consequently, Applicants identified the errors in the Restriction Requirement and request the Examiner to reconsider this requirement (*see* MPEP 821.01).

In the event that the Restriction Requirement is made final, Applicants respectfully request rejoinder of the unelected species upon allowance of the generic base claim. It is submitted that withdrawn claims 16 and 39-42 depend from claim 1, which is now allowable. Therefore, rejoinder is proper (MPEP 821.04).

III. Claim Rejections – 35 U.S.C. § 101

Claims 1-28, 36-38, and 43-44 stand rejected under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. The Office Action states:

In the instant case, at least one embodiment of the claimed invention merely manipulates data sequences and performs a series of calculations without transforming an article or physical object to a different state or thing outside a computation device.

Furthermore, the invention does not produce a useful, concrete and tangible result. Since the process merely manipulates data sequences and performs a series of calculations, and the process can be performed entirely in a computer or machine or human mind without using or making available for use the results of the manipulation to enable the functionality or usefulness to be realized.

(Office Action, p. 4).

In accordance with the Examiner’s suggestion, Applicants have added a step to independent claims 1 and 18, which recites the displaying of the corresponding pairs of data

points not eliminated by earlier steps in the method to a user. Thus, the claimed methods produce a data set for the user in which the unreliable data has been removed. Support for this amendment can be found throughout the application as filed, including, but not limited to, paragraph [0084] and FIG. 3, which depicts the results of the method of claim 1 applied to an exemplary embodiment (gene expression in meningioma). The displayed results indicate to the researcher which genes are up- or down-regulated in the particular disease state (*see* paragraphs [0085] to [0086]). (Specification, pp. 41-44).

Compliance with § 101 may be established where the claimed invention produces a useful, concrete, and tangible result. The process claimed in the pending claims produces a useful, concrete, and tangible result. MPEP § 2106 states that the “tangible requirement does require that the claim must recite more than a 35 U.S.C. 101 judicial exception, in that the process claim must set forth a practical application of that judicial exception to produce a real-world result.” MPEP § 2106 further states that “[i]t is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted” Such practical method and means of producing a beneficial result is reflected in independent claims 1 and 18. Specifically, the claimed methods output a data set to the user in which the unreliable data has been removed (*See* Specification, paragraph [0012]). The beneficial, real-world result is the elimination of indistinguishable differentials from data generated from the comparison of the two samples which results in the removal of unreliable data, providing a more robust comparison. The present methods may be used by, for example, persons performing gene expression analysis, protein expression profiling, nucleic acid sequence profiling, or analyzing oligochip data, seismic data, chromatographic data, thermal gravimetric data, and economic data. (*See generally* paragraphs [0018] and [0025]-[0028]). The result of the analysis is displayed to a user. Consequently, claims 1-28 and 36-44 recite tangible subject matter.

Accordingly, Applicants respectfully submit that claims 1-28 and 36-44 as amended, satisfy the requirements of 35 U.S.C. § 101, and request that the Examiner withdraw this rejection.

IV. Conclusion

Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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